REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

I. Status of the Claims

Claim 18 was previously cancelled. Claims 1 and 19 have been amended to recite the concentration of pullulan and claim 2 has been amended to delete the corresponding recitation.

Applicants acknowledge the finality of the Office Action. Because: (i) the amendments are made to delete recitations and to incorporate recitations from a dependent claim, respectively, (ii) the amendments do not require any additional search, and (iii) the amendments place the application in condition for allowance, or at least in better condition for appeal, Applicants respectfully request entry of the claim amendments.

Upon entry, claims 1-17 and 19-57 will be pending, with claims 27 and 31-36 withdrawn from consideration.

II. Rejection of Claims under 35 U.S.C. §103(a)

Claims 1-17, 19-26, 28-30, and 37-57 are rejected under 35 U.S.C. §103(a) for alleged obviousness over U.S. Patent No. 6,287,596 to Murakami et al. ("Murakami"). Applicants respectfully traverse the rejection.

Murakami discloses a rapidly disintegratable composition, which requires the presence of a mixture of erythritol and an excipient (column 4, lines 6-20). Particularly, the amount of erythritol and the excipient must fall within a certain range. Murakami further describes that "[a]mounts [of erythritol and the excipient] less than 30% by weight lead to insignificant contribution of these ingredients, resulting in poor disintegration and dissolution" (column 5, lines 32-39).

In contrast, the claimed invention is directed to a solid dosage form having a friability of less than about 1%. The claimed solid dosage form comprises at least one active agent and pullulan in the range of about 99.9% to about 0.1% (w/w). Therefore, the claimed invention is distinguished from Murakami in the aspects: (i) that the prior art does not teach or suggest a composition having a friability of less than about 1%; (ii) that the claimed dosage form does not require the presence of erythritol, which is mandatory for the prior-art composition; and (iii) that the claimed dosage form requires the presence of pullulan, which is only an optional additive for the prior-art composition (see Murakami, column 7, lines 10-12 and 28).

The Examiner asserts that "friability is a property of the product" (Office Action, page 3, line 18). Pursuant to MPEP 2112, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)." Nevertheless, because the claimed dosage form is distinguished from the prior-art composition in their ingredients, the Examiner has not established an "inherency" in the present case.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under Section 103(a).

III. Rejection of Claims under 35 U.S.C. §112, second paragraph

Claims 13 and 49 are rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. Applicants respectfully traverse the rejection.

The Examiner contends that "solid dosage forms are not aerosols, the aerosols may have suspended solid particles but the aerosol dosage form itself is not a solid dosage form..." (Office Action, page 7, lines 4-6). Nevertheless, an aerosol formulation can be delivered via a dry powder inhaler, which does not require the presence of any gas propellant or liquid propellant. To this end, Applicants submit herewith Exhibit A, which is an excerpt of the FDA Guidance for

Industry Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products (November 13, 1998, downloaded from http://www.fda.gov/cder/guidance/2180dft.htm). For example, the Guidance describes that "[w]hereas MDIs use energy stored in a liquefied gas propellant under pressure for aerosolization and dispersion, DPIs may rely on several energy sources, including energy from patient inspiration, from compressed gas, or from a motor-driven impeller" (page 4, last four lines). Accordingly, because the Examiner's contention is based on a misunderstanding of the aerosol formulation, withdrawal of the rejection is respectfully requested.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Sept. 29, 2008

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